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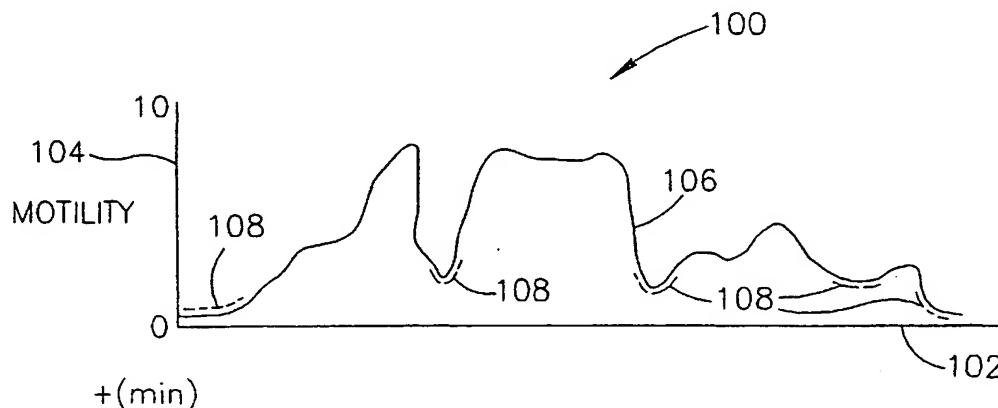
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(54) Title: MOTILITY ANALYSIS WITHIN A GASTROINTESTINAL TRACT



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(57) Abstract: A system and method for measuring and analyzing motility within a body lumen such as the gastrointestinal (GI) tract, where an in vivo imaging device such as a capsule captures images and transmits the images to a processor, which calculates the motility of the device based on comparison of the images. Preferably, the processor compares the intensity of pairs of images or of elements of pairs of images, generates a variance for the compared images, and calculates the motility of the imaging device from the variances. The motility data may be presented to a user in various manners; for example, a plot of motility over time may be generated, or indications of low motility may be presented to the user of the system.

## MOTILITY ANALYSIS WITHIN A GASTROINTESTINAL TRACT

### FIELD OF THE INVENTION

5 The present invention relates to a method and system for analysis of motility within a body lumen, such as within the gastrointestinal (GI) tract.

### BACKGROUND OF THE INVENTION

10 Normal peristalsis within a GI tract is responsible for transporting swallowed food and aiding in digestion and eventual evacuation. Peristalsis results in pressure waves moving along the GI tract, in turn resulting in the motility of a bolus within the GI tract. Thus, changes in motility along the GI tract may indicate normal conditions such as food passing from one section of the GI tract to another (such as passage from the stomach to the small intestine or 15 passage from the small intestine to the large intestine). Certain pathological conditions can alter the normal motility within the GI tract. Low motility may be caused by an obstruction or blockage or by other pathological conditions. It is often difficult to detect areas of low or abnormal motility within the GI tract, since these areas may be in difficult to reach locations. It is difficult to "see" inside the tract, especially in sections that are hard to reach via conventional 20 methods, such as the small intestines. Motility is the result of complex neuro-physiological processes. Motility disorders may be caused by nervous disorders, and may not necessarily be visible as, for example, physiological changes in the intestinal tissue.

Various in vivo measurement systems for examining a body lumen are known in the art. A commonly known and used type of system is an endoscope. Endoscopes are devices which 25 include a tube (either rigid or flexible) and an optical system, and which are introduced into the body to view the interior. The range of endoscopes – the portion of the GI tract, which

endoscopes are capable of viewing – is limited. Endoscopes are usually not helpful in providing information on GI tract motility. Probes, such as pressure probes, may be used to measure peristaltic pressure waves. Other systems that may be used for obtaining information on GI tract motility include dissolvable vehicles containing non dissolving markers that are visible by X-ray. The vehicle is ingested and the progression of the markers, which are released in the GI tract once the vehicle is dissolved, can be followed by X-ray. This method, however, can not be used for continuous monitoring and also exposes the patient to hazardous X-rays.

A non hazardous system and method for monitoring and/or analyzing movement along the entire GI tract is needed, *inter alia*, for facilitating the understanding of GI tract motility and for expanding diagnostic (and perhaps therapeutic) possibilities in the GI tract.

## SUMMARY OF THE INVENTION

An exemplary embodiment of the system and method of the present invention measures and analyzes motility within a body lumen such as the GI tract. In another embodiment of the invention a method is provided for diagnosis of *in vivo* conditions in the GI tract of a patient.

In one embodiment an *in vivo* imaging device such as an ingestible imaging capsule captures images and transmits the images to a processor, which calculates the motility of the device based on comparison of the images. In one embodiment the processor compares the intensity of pairs of images or of elements of pairs of images, generates an average difference for the compared images, and calculates the motility of the imaging device from the average differences. In other embodiments indicators, such as radio frequency (RF) signals, strain gauges, velocity meters or accelerometers may be used to calculate the motility of a device. In another embodiment a geometrical location or *in vivo* position of the device may be determined for later calculation of the motility. The motility data may be presented to a user in various

manners; for example, a plot of motility over time may be generated, or indications of low or abnormal motility may be presented to the user of the system.

According to an embodiment of the invention motility analysis data is examined for at least one parameter, the parameter is compared to a reference and at least one condition in the 5 GI tract is deduced from the comparison.

### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

10 Fig. 1 is a schematic illustration of an in vivo imager system, according to one embodiment of the present invention;

Figs. 2A and 2B show a simplified series of images, which may be captured by the vivo imager system of Fig. 1;

15 Fig. 3 depicts a motility chart produced by the system of Fig. 1, according to one embodiment of the present invention;

Fig. 4 is a flow chart showing the steps for determining the motility of a device recording images from a body lumen according to an exemplary embodiment of the present invention; and

20 Figs. 5A and 5B are histograms used to calculate motility according to an embodiment of the present invention.

## DETAILED DESCRIPTION OF THE INVENTION

In the following description, various aspects of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well known features may be omitted or simplified in order not to obscure the present invention.

The present invention relates to a method and system for analyzing motility within a GI tract and for displaying motility to a user such as a health professional, who may use such data to, for example, diagnose pathologies. In an exemplary embodiment of the present invention, the motility of a capsule or other vehicle, which is propelled through the GI tract by the natural action of the GI tract is measured, giving an indication of the motility in the GI tract, in different portions of the GI tract. In one embodiment, the motility of the vehicle is calculated via an analysis of sequential images captured by the vehicle; the greater the difference between sequential images, the greater the motility.

Reference is made to Fig. 1, which shows a schematic diagram of an in vivo imaging system according to one embodiment of the present invention. In an exemplary embodiment, the system comprises a capsule 40 having an imager 46, for capturing images, an illumination source 42, for illuminating the body lumen, and a transmitter 41, for transmitting image and possibly other information to a receiving device. An optical system (not shown), including, for example, lenses or mirrors, may aid in focusing reflected light onto the imager 46. The capsule 40 is swallowed by a patient and preferably traverses the patient's GI tract. In alternate embodiments the capsule 40 may have different configurations and include other sets of components.

Preferably, while the capsule 40 traverses a patient's GI tract, the capsule 40 transmits image and possibly other data to components located outside the patient's body, which receive and process the data. Preferably, located outside the patient's body in one or more locations, are an image receiver 12, preferably including an antenna or antenna array, an image receiver storage unit 16, a data processor 14, a data processor storage unit 19, and an image monitor 18, for displaying, *inter alia*, the images recorded by the capsule 40 and motility information. In one embodiment, the image receiver 12 and image receiver storage unit 16 are small and portable, and are worn on the patient's body during recording of the images. Optionally, data processor 14, data processor storage unit 19 and monitor 18 may be part of a personal computer or workstation, which includes standard components such as processor 14, a memory, a disk drive, and input-output devices, although alternate configurations are possible.

Data processor 14 may include any standard data processor, such as a microprocessor, multiprocessor, accelerator board, or any other serial or parallel high performance data processor. Image monitor 18 may be a computer screen or a conventional video display, but may, in addition, be a printer or any other device capable of providing an indication of image and/or position data.

Preferably, the imager 46 is a suitable CMOS camera, such as a "camera on a chip" type CMOS imager specified by Given Imaging Ltd. of Israel and designed by Photobit Corporation of California, USA. In alternate embodiments, the imager 46 may be, for example, a CCD. The illumination source 42 may be, for example, a light emitting diode.

In operation, imager 46 captures images and sends data representing the images to transmitter 41, which transmits images to image receiver 12 using, for example, electromagnetic radio waves. Image receiver 12 transfers the image data to image receiver storage unit 16. After a certain period of time of data collection, the image data stored in storage unit 16 is sent to data processor 14 or data processor storage unit 19. For example, the image receiver storage

unit 16 may be taken off the patient's body and connected to the personal computer or workstation which includes the data processor 14 and data processor storage unit 19 via a standard data link, *e.g.*, a serial or parallel interface of known construction. The image data is then transferred from the image receiver storage unit 16 to the data processor storage unit 19.

5 Data processor 14 analyzes the data and provides the analyzed data to the image monitor 18, where a health professional views, for example, the image data and motility information.

The image data collected and stored may be stored indefinitely, transferred to other locations, or manipulated or analyzed. A health professional may use the images to diagnose pathological conditions of the GI tract, and, in addition, the system may provide information 10 about the location of these pathologies. While, using a system where the data processor storage unit 19 first collects data and then transfers data to the data processor 14, the image data is not viewed in real time, other configurations allow for real time viewing. In such systems, image motility may be calculated and displayed in real time.

The image monitor 18 presents the image data, preferably in the form of still and 15 moving pictures, and in addition may present other information. In an exemplary embodiment, such additional information may include, but is not limited to, absolute time elapsed for the current image being shown and the relative or absolute motility of the capsule 40, over the course of the capsule's travel through the GI tract, and/or at the time corresponding to the current image being displayed. Absolute time elapsed for the current image being shown may 20 be, for example, the amount of time that elapsed between the moment the capsule 40 was first activated and the image receiver 12 started receiving transmissions from the capsule 40, and the moment that the current image being displayed was captured. Various methods may be used to display the motility of the capsule 40; such methods are discussed below. In an exemplary embodiment, the various categories of information are displayed in windows. Multiple 25 monitors may be used to display image and other data.

Preferably, the image data recorded and transmitted by the capsule 40 is digital color image data, although in alternate embodiments other image formats may be used. In an exemplary embodiment, each frame of image data includes 256 rows of 256 pixels each, each pixel including data for color and brightness, according to known methods. For example, in each pixel, color may be represented by a mosaic of four sub-pixels, each sub-pixel corresponding to primaries such as red, green, or blue (where one primary is represented twice). The brightness of the overall pixel is recorded by a one byte (*i.e.*, 0-255) brightness value. Preferably, images are stored sequentially in data processor storage unit 19. The stored data is comprised of one or more pixel properties, including color and brightness.

10 While, preferably, information gathering, storage and processing is performed by certain units, the system and method of the present invention may be practiced with alternate configurations. For example, components providing for motility analysis may be located inside a capsule or, alternately, on a portable device worn on the patient. Furthermore, the components gathering image information need not be contained in a capsule, but may be contained in any 15 other vehicle suitable for traversing a lumen in a human body, such as an endoscope, stent, catheter, needle, etc.

The in vivo imager system may collect a large volume of data, as the capsule 40 may take several hours to traverse the GI tract, and may record images at a rate of, for example, two images every second, resulting in the recordation of tens of thousands of images. The series of 20 still images collected may later be presented as still images or as a moving image of the traverse of the GI tract. The image recordation rate (or frame capture rate) may be varied; for example, the image recordation rate may be varied based on capsule motility. While in the GI tract, the capsule 40 undergoes intermittent motion with long residence time at some positions. These periods of long residence may be normal or can be due to pathologies, such as blockages, within 25 the digestive tract. The system and method of the present invention aids health professionals in

monitoring the capsule motion and in diagnosing and locating, for example, areas of blockage. In addition, changes in motility may be indicative of a normal condition such as the passage of the capsule 40 from one section of the GI tract to another, and thus the system and method of the present invention may use motility data to determine the position of the capsule 40 or other 5 diagnostic device.

In an exemplary embodiment, each image  $P_i$  in the data stream of images is compared to its predecessor image  $P_{i-1}$  (or to other previous image  $P_{i-n}$ ) to determine the motility of the capsule 40 during the time between the capture of the two images. Various methods of determining motility based on image comparison may be used. In an exemplary embodiment, 10 the system and method analyze image similarity to obtain a measure of motility. It can be assumed that the more similar two compared images are, the slower the movement of the capsule 40 between the times the two images are captured. In an extreme situation – if the two compared images are identical – it can be assumed the capsule 40 has not moved between the times the two images were captured. If two compared images differ greatly, it is an indication 15 that the capsule 40 was moving quickly between the times of capture of the images. This concept is illustrated further in Figs. 2A and 2B.

Figs. 2A and 2B show a simplified series of images, which may be captured by the vivo imager system of Fig. 1. Referring to Figs. 2A and 2B, a comparison of images provides information about the speed of the capsule 40. In Fig. 2A, several consecutive images are 20 shown in which a specific point X is located in approximately the same location within each of the images. In Fig. 2B, the same point X is located in varying positions within the images, taken over the same period of time. It can be inferred that the images shown in Fig. 2A were taken by an imager whose position did not change by much between the times each image was taken, and thus which had relatively low motility. It can be inferred that the images shown in 25 Fig. 2B were taken by an imager which is moving more rapidly.

Preferably, data processor storage unit 19 stores a series of images recorded by a capsule 40. The images may be combined consecutively to form a moving image of the images the capsule 40 recorded as it moved through a patient's GI tract. This moving image may be displayed in a window on monitor 18. The moving image may be frozen to view one frame, 5 speeded up, or reversed; sections may be skipped; or any other method for viewing an image may be applied to the moving image. While the following discussion relates to the case where data from a capsule 40 is stored for later use, the system and method of the present invention may be used with systems allowing for real time viewing of image data.

In an exemplary embodiment, to determine the motility of the capsule 40 at various 10 points during its journey through the GI tract, data processor 14 first receives image data from data processor storage unit 19. Data processor 14 then compares each image  $P_i$  in the data stream to its predecessor image  $P_{i-1}$  (or  $P_{i-n}$ ) to determine the motility of the capsule 40 during the time between the capture of the two images.

The comparison of images may be made on a pixel-by pixel basis or, alternatively, on a 15 pixel cluster basis. In alternate embodiments, images may be compared without division into sections such as pixels or clusters. In an exemplary embodiment, the 256x256 pixel grid of each image is divided into a 32x32 grid of pixel clusters, to form 1,032 clusters. In alternate embodiments, other methods of dividing an image may be used. Based on the comparison of the two images, data processor 14 calculates the relative motility for the capsule 40 that 20 captured the images for the time period between the capture of the two images. In an exemplary embodiment, the resulting motility value at a certain point is a relative number on a certain scale, which indicates the motility of the capsule 40 relative to other points in the capsule's traverse of the GI tract. In alternate embodiments, absolute motility may be calculated.

The motility calculation is repeated for all or a set of images in the series of images, and 25 a series of motility values is generated. The resulting motility values may be presented to the

user in various manners. Preferably, the monitor 18 includes a window displaying an image frame or a moving image, a window showing the absolute time elapsed in the image series for the frame being displayed (or the current point in the moving image), and a window including a chart of the relative motility of the capsule 40 plotted against time. An indication may be 5 provided on the display on monitor 18 connecting certain motility values, or regions having low motility or certain motility patterns, to images or sections of the moving image. The user may be able to indicate certain motility values or a portion of the motility chart or plot by, for example, clicking with a mouse, and have displayed the corresponding still or moving image.

Additional windows may display other data. For example, the position of the capsule 40 10 as it traverses the GI tract may be graphed as a two-dimensional rendering of the three-dimensional path; such data may be combined with or linked to image or motility data. Areas of low motility, or areas of altered or abnormal patterns of motility, may be indicated on such a capsule path representation by using, for example, color changes or labels.

In one embodiment, a spectral analysis of the motility data may be performed, and the 15 spectral analysis may be presented to the user or may be used for diagnostic or other purposes. In a normal human GI tract, peristaltic waves are typically generated with some repetition. A spectral analysis, according to known methods, of the peristaltic waves of different time periods or sections of the series of motility data, may be performed and, for example, presented to the user. Such a spectral analysis may present, for example, the frequency of repetition of peristaltic 20 waves at different times or positions in a vehicle's travel through the GI tract. In alternate embodiments, other visual indications of motility may be provided.

According to one embodiment of the invention, motility data can be examined for at least one parameter or measurement that may be presented as, for example, a specific pattern or representation of a pattern in a spectral analysis of the motility data or a specific repetition or 25 representation of a repetition of peristaltic waves. The parameter, possibly represented by a

pattern or specific patterns, can be compared to a reference, such as a parameter value in a normal or healthy individual or a specific pattern typical of a pathological condition in the GI tract. The comparison results can indicate, for example, a prevailing condition (or conditions) in the GI tract, thereby providing a diagnostic tool for identifying conditions in the GI tract. For 5 example, a spectral analysis may be performed on the motility of an in-vivo device. The spectral analysis may be represented, for example, as a graph of movement waves over time; other ways of representing a spectral analysis may be used. A pattern matching module (for example, processor 14 operating according to software) may seek to match the recorded spectral analysis to spectral analyses corresponding to various conditions, and a match or near match 10 may be reported to a user.

Fig. 3 depicts a motility chart produced, for example, by the system of Fig. 1, according to one embodiment of the present invention. The plot or chart 100 includes a time axis 102, a relative motility axis 104, and a motility plot or graphing 106. Preferably, if the health professional indicates a certain point along the motility chart, using, for example, a pointing 15 device such as a mouse, the corresponding image appears in the image window. While, in an exemplary embodiment, the relative motility is expressed in arbitrary units (for example, 0 to 10, adjusted logarithmically), other methods of expressing motility may be used, and absolute motility may also be expressed.

The chart 100 may include indications of low motility 108, which may be, for example, 20 marks or colored or shaded regions indicating areas where motility is low enough to warrant investigation by a health professional. The data processor 14 may filter for certain patterns of motility, where such patterns may commonly indicate either normal conditions, such as passage between areas of the GI tract, or pathological conditions. Such conditions may be labeled on the motility chart. In response to such indications of low motility, the health professional may click

or otherwise indicate the area on the motility chart in question, and view images (still or moving) of the corresponding area in the GI tract.

Any number of methods may be used to analyze the image data to form motility data. For example, motility analysis may be based on a calculation of the difference in a given property between corresponding pixels of two, not necessarily consecutive, frames; a calculation of the cross-correlation function between two, not necessarily consecutive, frames; a calculation of the changes of local statistical distributions in two, not necessarily consecutive, frames; or a calculation of the changes between corresponding local statistical distributions in two, not necessarily consecutive, frames. Local statistical distributions may include, but are not limited to, the mean, the variance, or the standard deviation of pixel clusters.

In an exemplary embodiment, each image in a pair of images being compared is divided into a number of sections. Each section in the first image is compared to the corresponding section in the second image. The variance of the difference of the brightness for the two sections, normalized by the number of sections, is calculated. The variance is used to ascertain the relative motility of the vehicle capturing images, which in an exemplary embodiment is capsule 40.

Reference is now made to Fig. 4, a flow chart showing the steps for determining the motility of a device recording images from a body lumen according to an exemplary embodiment of the present invention.

In step 200, image data is recorded by the capsule 40 and transmitted to the data processor storage unit 19. In step 202, data processor 14 receives from data processor storage unit 19 images  $P_i$  and  $P_{i+x}$ , where  $x$  is usually, but not necessarily, 1. If the stream of images is too lengthy or rapid, a decimation may be performed and non-adjacent images may be compared, e.g., image  $P_i$  and  $P_{i+x}$ , where  $x > 1$ .

In step 204, data processor 14 may divide each of the two images into pixel clusters, sections or cells. In an exemplary embodiment, each image  $P_i$  is divided into 1024 clusters  $A_i(m,n)$ , where  $1 < m < 32$  and  $1 < n < 32$ .

In step 206, data processor 14 calculates the average intensity  $I_{A_i(m,n)}$  of each cluster  $A_i(m,n)$  of each of image  $P_i$  and  $P_{i+x}$ . Preferably, the intensity value for a cluster is the average of the brightness values for the pixels in the cluster. A matrix of the intensities of the clusters may be formed for each image. Alternate methods of calculating intensity may be used; for example, color data may be used to compare images.

In step 208, data processor 14 determines the absolute value  $D_i(m,n)$  of the difference of the average intensities  $I$  of  $A_i(m,n)$  and  $A_{i+x}(m,n)$  of corresponding clusters  $A(m,n)$  in the frames  $P_i$  and  $P_{i+x}$ .  $D_i(m,n)$  is defined as:

$$D_i(k,l) = |I_{A_i(k,l)} - I_{A_{i+x}(k,l)}|$$

A matrix of the absolute values of differences is formed, one value being generated for each cluster compared.

In step 210, data processor 14 determines the average difference (*Diff*) between the two images. In an exemplary embodiment, the average difference is calculated by first subtracting from each absolute value in the matrix created in step 208 the average value of all the differences in the matrix, summing the resulting values, taking the square root of the resulting sum, and dividing by the number of the differences in the matrix (in an exemplary embodiment 1024). This may be expressed by the formula:

$$Diff = \sum_{m=1,32; n=1,32} D_i(m,n) / 1024$$

where *Diff* corresponds to the average of the values in the difference matrix.

In an exemplary embodiment, the resulting average difference is a value from 0 to U, where U is an arbitrary upper limit which depends upon the input parameters. A low average difference indicates that the measured value (in an exemplary embodiment, brightness) varies little between the compared frames, and a high value of the average difference indicates that the measured value varies a large amount. A low difference is an indication of low motility, as, if the capsule 40 is not moving quickly, the images in the two compared frames will not vary by a large amount.

In step 212, if more frames exist in the image stream, data processor 14 returns to step 10 202. If no more frames exist, data processor 14 proceeds to step 214. At this point, the difference data exists as a series of difference values, one for each frame pair analyzed, preferably X-1 variances, where X is the number of frames analyzed.

In step 214, data processor 14 may normalize or decimate the resulting difference data to an arbitrary scale. This normalized data represents the relative motility of the capsule 40. In an 15 exemplary embodiment, each difference datum, represented as a value from 0-U, is normalized to a number between 0 and 10; other ranges may be used. The normalization process may be linear or may be non-linear – for example, a logarithmic function may be used. In alternate embodiments, other normalization or decimation functions may be used; for example, the difference data may be translated to a set of integers. During normalization, various functions, 20 such as logarithmic functions, may be applied to the data.

In step 216, data processor 14 provides an indication of motility for the capsule 40. In an exemplary embodiment, data processor 14 creates a plot or graph of relative motility over time for display on the monitor 18 using the normalized values created in step 214. Data processor 14 may augment the graph with indications of low motility or indications of certain

conditions. For example, sections of the graph where motility falls below a certain threshold may be marked in a certain color or pattern, or may be otherwise labeled.

In alternate embodiments, other methods of analyzing the image data to form motility data may be used. For example, for each frame pair, data processor 14 may organize the 5 difference values  $D_i(k,l)$  into a chart, for example, a histogram, as shown in Figs. 5A and B. Figs. 5A and B depict histograms used to calculate motility according to an embodiment of the present invention. Referring to Figs. 5A and B, the absolute value  $D_i(m,n)$  of the difference is plotted on the x-axis of the histograms and the number of corresponding pairs of cells,  $A_i(m,n)$  and  $A_{i+x}(m,n)$ , which have a difference of magnitude  $D_i(k,l)$ , is plotted on the y-axis. The 10 histogram of in Fig. 5A represents a histogram of cells in relatively similar frames, while the histogram of Fig. 5B shows a histogram of cells in significantly different frames. It should be readily apparent that if two images are similar, the histogram of the differences in the cells of these images are concentrated at low values of  $D_i(m,n)$ . It should also be readily apparent that the center of mass  $CM_a$  (the average difference between the two images) of the histogram 15 shown in Fig. 5A has a smaller value of D than the center of mass  $CM_b$  of the histogram shown in Fig. 5B, and corresponds to a slower moving capsule 40. To calculate the difference between the two frames, processor 14 determines the centers of mass CM of the histograms corresponding to the two frames, and creates a difference value based on the location of the CM.

In another embodiment image analysis may be used to determine the location of the 20 capsule 40 in vivo (for example by identifying image parameters that are typical to a specific region in the GI tract) and the position information together with known factors; either the time that has elapsed during the translocation of the capsule 40 or the velocity of the capsule 40 along its path, can be used to calculate the motility. Similarly, the location of the capsule may be determined by other known methods and the location information can be used to calculate 25 motility.

In alternate embodiments, methods of measuring motility may be used which are not based on image analysis. For example, the capsule 40 may include an accelerometer, which determines the instantaneous acceleration of capsule 40 as it moves through the GI tract. An integrator may convert the acceleration data to velocity data, and this velocity data may be used by the data processor to determine motility. Alternately, a pressure sensor or shear gauge attached to the capsule 40 may detect peristaltic induced pressure or movement exerted by the walls of the small intestine. The relationship between pressure and velocity may be determined empirically, and then utilized to determine the velocity or relative velocity of the capsule 40. A sensor in the capsule 40 may detect movement relative to an artificially induced magnetic field, which is generated in the area of the patient's GI tract. The magnetic field induces a current in a coil in the sensor, whose magnitude is a function of the velocity of the coil through the field. Data on the induced current is converted to motility information. Further, external sensors may also be used, such as a Doppler ultrasound unit, which continuously tracks the capsule 40. Additionally, the receiver 12, which, according to one embodiment is adapted to receive RF signals from the transmitter 41, may be used to monitor the intensity of the transmitted signal, whereas signals of unchanging intensities indicate that the transmitter 41 (and hence the capsule 40) is unmoving and signals of different intensities indicate that the transmitter 41 is moving. One or more of the above methods, or other methods, may be combined to provide a determination of capsule motility.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the invention is defined by the claims that follow:

**CLAIMS**

1. A method for measuring and analyzing motility within a body lumen, the method comprising the steps of:

accepting images acquired by a vehicle disposed within said body lumen; and  
5 calculating a motility of the vehicle within said body lumen based on comparison of said accepted images.

2. The method as in claim 1, wherein said vehicle is a capsule.

10 3. The method as in claim 1, wherein said motility is relative motility.

4. The method as in claim 1, wherein said motility is absolute motility.

5. The method as in claim 1, wherein said comparison is a comparison of image intensity.

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6. The method as in claim 1, further comprising the steps of:

comparing two images;

generating a variance for the two images; and

repeating the comparing and variance generating steps for a plurality of image pairs to  
20 generate a series of variance values.

7. The method as in claim 1, wherein the step of comparing the images includes, for a pair of images to be compared, at least the steps of:

dividing each image into sections;

comparing corresponding sections of the images to produce a matrix of difference values; and

calculating a variance between the two images, the variance based on a function of the matrix.

5

8. The method as in claim 1 wherein said vehicle transmits image data from a gastrointestinal tract.

9. The method as in claim 1, comprising displaying an indication of motility.

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10. The method as in claim 1, comprising creating a plot which displays motility as a function of time.

11. The method as in claim 10, comprising:

15

allowing a user to indicate a point on the plot; and

displaying to the user a set of images corresponding to said point on the plot.

12. The method as in claim 1, comprising the step of providing a visual indication of which of the images correspond to a motility which is below a threshold.

20

13. A system for measuring and analyzing motility within a body lumen, the system comprising:

an image storage memory accepting images acquired by a vehicle disposed within said body lumen; and

an image processor calculating a motility of the vehicle within said body lumen based on comparison of properties of said accepted images.

14. The system as in claim 13, wherein said vehicle is a swallowable vehicle.

5

15. The system as in claim 13, wherein said vehicle is a capsule.

16. The system as in claim 13, wherein said motility is relative motility.

10 17. The system as in claim 13, wherein said motility is absolute motility.

18. The system as in claim 13, wherein said comparison is a comparison of image intensity.

19. The system as in claim 13, comprising a processor performing the steps of:

15 comparing two images;  
generating a variance for the two images; and  
repeating the comparing and variance generating steps for a plurality of image pairs to  
generate a series of variance values.

20 20. The system as in claim 13, wherein said vehicle includes a transmitter.

21. The system as in claim 13, comprising a display on which a plot of motility as a function of time is displayed.

25 22. The system as in claim 21, comprising:

an input device accepting an indication from a user of a point on the plot, wherein in response to said indication a set of images corresponding to said point on the plot is displayed on said display.

5 23. A system for measuring and analyzing motility within a body lumen, the system comprising:

an image storage means for accepting images acquired by an image capture means disposed within said body lumen; and

10 10 24. The system as in claim 23, wherein said image capture means is disposed within a swallowable vehicle.

15 25. The system as in claim 23, wherein said image capture means is disposed within a capsule.

26. The system as in claim 23, wherein said motility is relative motility.

20 27. The system as in claim 23, wherein said motility is absolute motility.

28. The system as in claim 23, wherein said comparison is a comparison of image intensity.

29. The system as in claim 23, comprising a processing means for:  
25 comparing two images;

generating a variance for the two images; and  
repeating, for a plurality of image pairs, comparing and generating a variance, to  
generate a series of variance values.

5 30. The system as in claim 23, wherein said image capture means includes a transmitting  
means.

31. The system as in claim 23, comprising a display means on which a plot of motility as a  
function of time is displayed.

10

32. The system as in claim 31, comprising:

an input means accepting an indication from a user of a point on the plot; wherein in  
response to said indication a set of images corresponding to said point on the plot is displayed  
on said display means.

15

33. A method for measuring and analyzing motility within a body lumen, the method  
comprising:

accepting images acquired by a vehicle disposed within said body lumen;  
comparing two images;  
20 generating a variance for the two images;  
repeating the comparing and variance generating steps for a plurality of image pairs to  
generate a series of variance values; and  
calculating a motility of said vehicle within said body lumen based on said series of  
variance values.

25

34. A method for measuring and analyzing motility within a body lumen, the method comprising:

accepting images acquired by a capsule disposed within said body lumen;  
comparing pairs of said images;  
5 calculating a motility of said capsule within said body lumen based on said comparisons;

and

creating a plot which displays motility as a function of time.

35. A method for measuring and analyzing motility within a body lumen, the method

10 comprising:

accepting images acquired by a vehicle disposed within said body lumen;  
comparing two images;  
generating a variance for the two images;  
repeating the comparing and variance generating steps for a plurality of image pairs to  
15 generate a series of variance values;  
calculating a motility of said vehicle within said body lumen; and  
providing an indication of motility.

36. A method for measuring and analyzing motility within a body lumen, the method

20 comprising:

accepting images acquired by a capsule disposed within said body lumen;  
comparing a set of images;  
generating a variance for the set of images;  
repeating the comparing and variance generating steps to generate a series of variance  
25 values;

calculating a motility of said capsule within said body lumen; and  
providing an indication of motility of the capsule.

37. A method for measuring and analyzing motility within a body lumen, the method  
5 comprising:

accepting images acquired by a capsule disposed within said body lumen; and  
calculating a motility of the capsule within said body lumen based on comparison of  
said accepted images.

10 38. A method for determining at least one condition in a GI tract comprising the steps of:

calculating a motility of a device within the GI tract;  
creating a spectral analysis of said motility;  
examining the spectral analysis for at least one parameter;  
comparing said parameter to a reference; and  
determining a condition, if any, in the GI tract based on the comparison.

15

39. The method according to claim 38 further comprising creating a plot, which displays  
motility as a function of time.

20 40. The method according to claim 38 comprising accepting images acquired by  
the device.

41. The method according to claim 38 wherein calculating the motility includes  
at least comparing images accepted from the device.

25 42. The method according to claim 38 wherein calculating the motility includes  
at least monitoring the intensity of RF signals transmitted from a capsule  
disposed within said GI tract.

43. The method according to claim 38, wherein said device is a capsule.
44. A system for determining at least one condition in a GI tract, the system comprising:
  - a receiver capable of receiving signals from a device within the GI tract; and
  - 5 a controller capable of:
    - calculating a motility of the device;
    - creating a spectral analysis of said motility;
    - examining the spectral analysis for at least one parameter;
    - comparing said parameter to a reference; and
  - 10 determining a condition, if any, in the GI tract, based on the comparison.
45. The system according to claim 44 wherein the controller is capable of creating a plot which displays motility as a function of time.
46. The system according to claim 44 wherein calculating the motility includes at least comparing images accepted from the device.
- 15 47. The system according to claim 44, wherein said device is a capsule.

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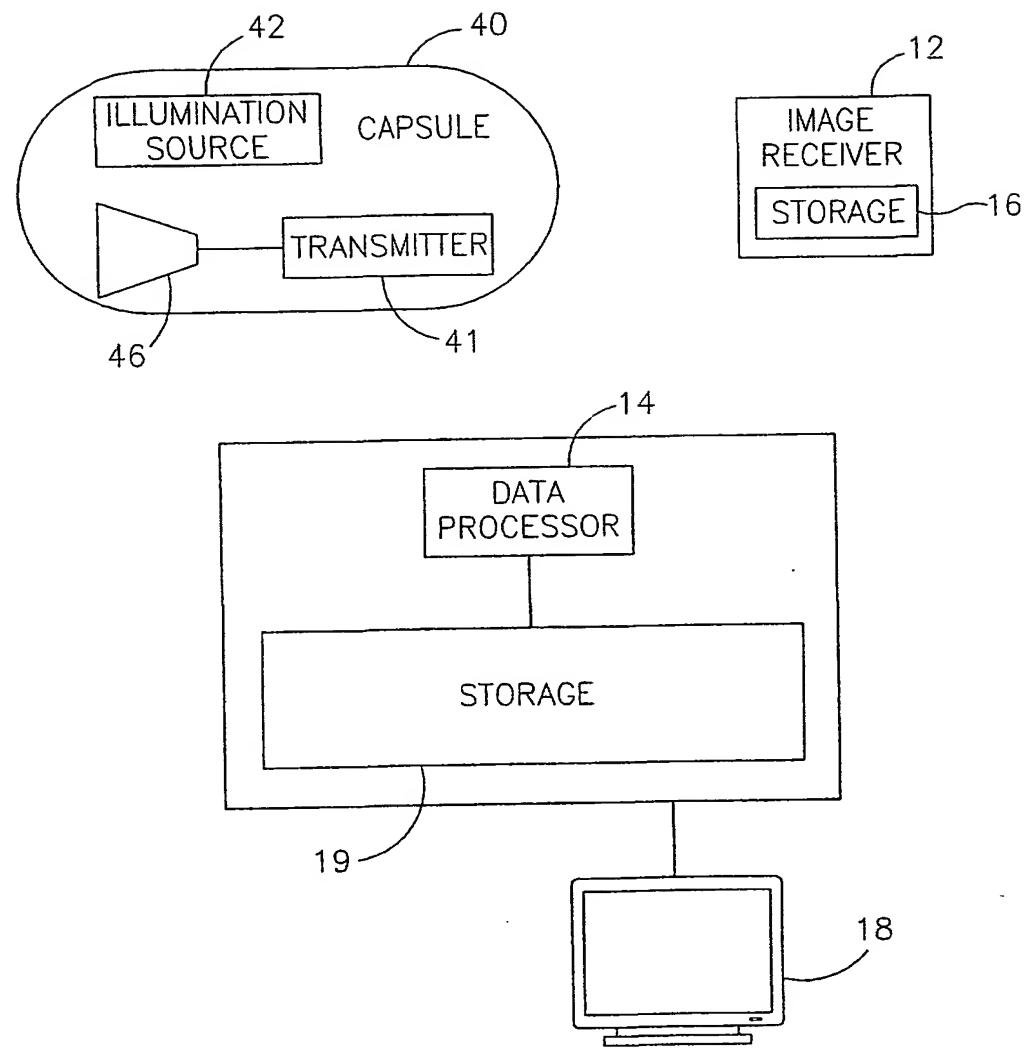


FIG.1

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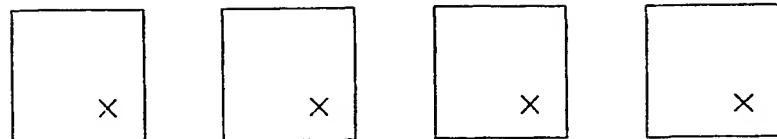


FIG.2A

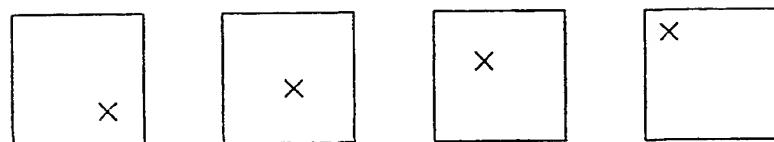


FIG.2B

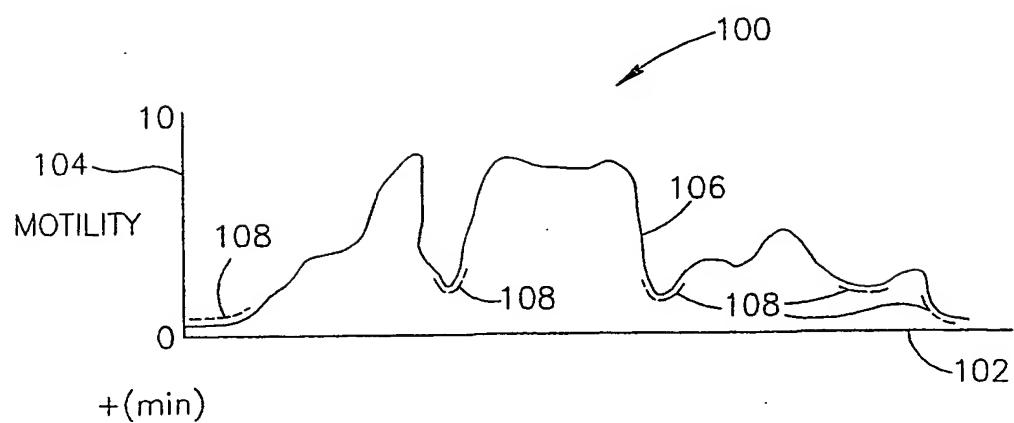


FIG.3

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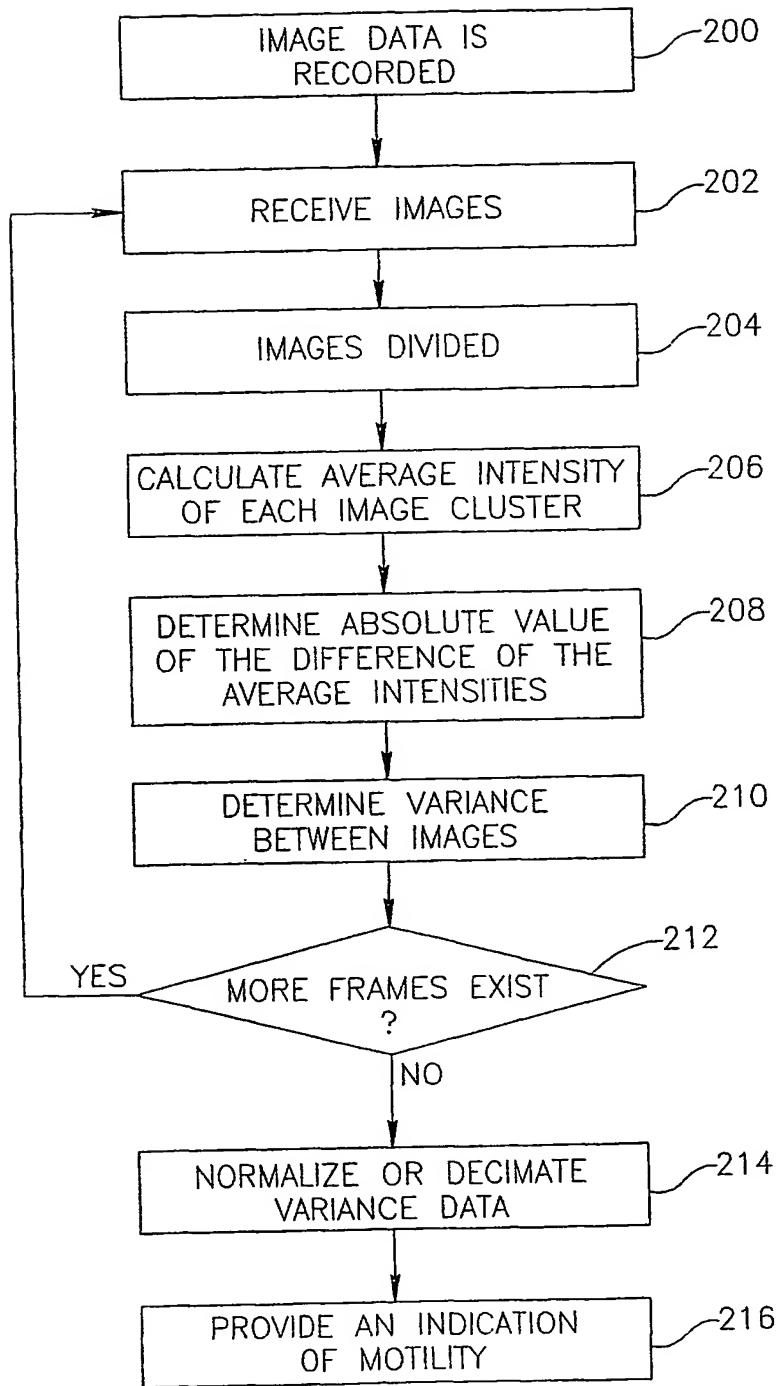


FIG.4

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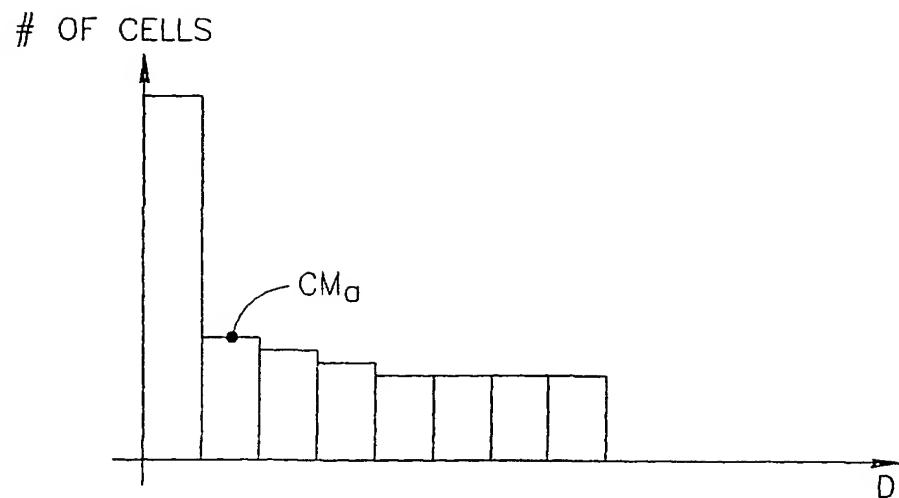


FIG.5A

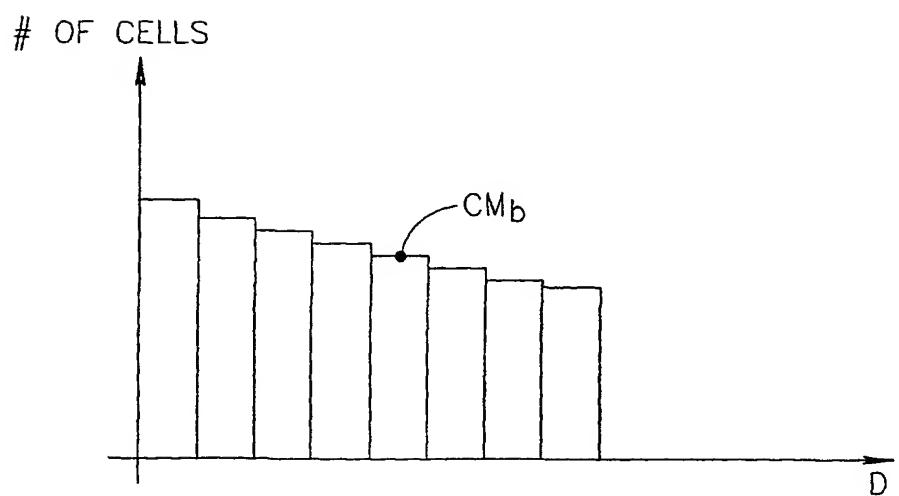


FIG.5B

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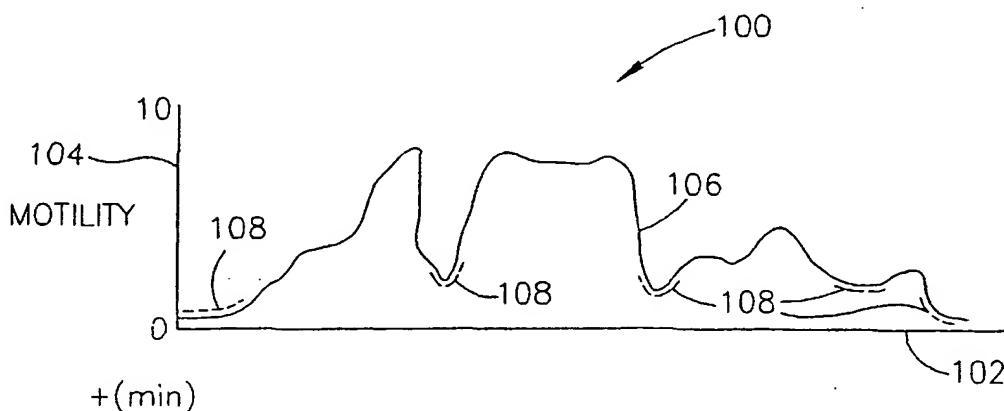
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(54) Title: MOTILITY ANALYSIS WITHIN A GASTROINTESTINAL TRACT



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(57) Abstract: A system and method for measuring and analyzing motility within a body lumen such as the gastrointestinal (GI) tract, where an in vivo imaging device such as a capsule captures images and transmits the images to a processor, which calculates the motility of the device based on comparison of the images. Preferably, the processor compares the intensity of pairs of images or of elements of pairs of images, generates a variance for the compared images, and calculates the motility of the imaging device from the variances. The motility data may be presented to a user in various manners; for example, a plot of motility over time may be generated, or indications of low motility may be presented to the user of the system.



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL02/00386

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 1/00  
 US CL : 600/310, 407, 425, 587, 595

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,604,531 A (IDDAN et al) 18 February 1997 (18.02.1997), see entire document.	1-47

Further documents are listed in the continuation of Box C.

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